

Claims

1. A process for manufacturing spherical pellets comprising
  - (a) a water-soluble active ingredient which is soluble, freely soluble or very  
5 soluble in water and preferably having a water-solubility of  $\geq 0.5$  g/ml;
  - (b) a spheronizing agent;
  - (c) a dry lubricant,said method comprising preparing a mixture of the active ingredient, the  
spheronising agent, the dry lubricant; and an amount of water which is less than  
10 5%, w/w relative to the total weight of the mixture; extruding said mixture to  
obtain an extrudate; and spheronising the extrudate to form spherical pellets.
2. A process according to claim 1 wherein the pellets are subsequently coated with a  
suitable coating.  
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3. A spherical pellet comprising
  - (a) a water-soluble active ingredient which is soluble, freely soluble or very  
soluble in water and preferably having a water-solubility of  $\geq 0.5$  g/ml;
  - (b) a spheronizing agent;
  - 20 (c) a dry lubricant.
4. A spherical pellet according to claim 3 comprising
  - (a) from 0.1 to about 50% of a water-soluble active ingredient which is soluble,  
freely soluble or very soluble in water and preferably having a water-solubility of  
25  $\geq 0.5$  g/ml;
  - (b) from about 25% to about 90% of a spheronizing agent;
  - (c) from about 2% to about 50% of a dry lubricant.
5. A spherical pellet according to claim 3 comprising
  - 30 (a) from about 1% to about 40% of a water-soluble active ingredient which is  
soluble, freely soluble or very soluble in water and preferably having a water-  
solubility of  $\geq 0.5$  g/ml;

(b) from about 20% to about 70% of a spheronizing agent;

(c) from about 10% to about 35% of a dry lubricant.

6. A spherical pellet according to claim 3 comprising

5 (a) from about 1% to about 50% of tramadol or a pharmaceutically acceptable acid-addition salt thereof, in particular tramadol hydrochloride;

(b) from about 15% to about 90% of micro-crystalline cellulose;

(c) from about 10% to about 35% of a glyceryl fatty ester, in particular a C<sub>22-26</sub> fatty acid mono-, di- or triglycerides mixture.

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7. A spherical pellet according to any of claims 3 - 6 wherein the pellet has a low water content.

8. A spherical pellet according to any of claims 3 - 7, wherein the active

15 ingredient in the pellets is tramadol, or a pharmaceutically acceptable acid addition salt thereof.

9. A spherical pellet according to any of claims 3 - 8 that is coated.

20 10. A pharmaceutical dosage form containing spherical pellets or coated spherical pellets as claimed in any of claims 3 - 9.

11. A dosage form according to claim 10, which is a capsule filled with pellets or coated pellets as claimed in any of claims 3 - 9.

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12. A process for manufacturing a pharmaceutical dosage form as claimed in claim 11 or 12, said method comprising filling the pellets into a suitable container, or in particular into a capsule.

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